US009950142B2

(12) **United States Patent**
Eversull et al.

(10) **Patent No.: US 9,950,142 B2**
(45) **Date of Patent: Apr. 24, 2018**

(54) **STEERABLE CATHETERS AND METHODS FOR MAKING THEM**

(71) Applicant: **CLPH, LLC**, Palo Alto, CA (US)

(72) Inventors: **Christian S. Eversull**, Palo Alto, CA (US); **Stephen A. Leeflang**, Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/842,828**

(22) Filed: **Sep. 1, 2015**

(65) **Prior Publication Data**

US 2016/0082226 A1 Mar. 24, 2016

Related U.S. Application Data

(60) Provisional application No. 62/044,331, filed on Sep. 1, 2014.

(51) **Int. Cl.**

A61M 25/01	(2006.01)
A61B 18/14	(2006.01)
A61B 18/00	(2006.01)
A61B 17/00	(2006.01)

(52) **U.S. Cl.**

CPC .... ***A61M 25/0147*** (2013.01); ***A61M 25/0136*** (2013.01); *A61B 18/1492* (2013.01); *A61B 2017/00327* (2013.01); *A61B 2018/00577* (2013.01); *A61B 2018/00821* (2013.01); (Continued)

(58) **Field of Classification Search**

CPC A61M 25/0147; A61M 25/0133; A61M 25/0136

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,413,107	A *	5/1995	Oakley	A61B 8/12 600/463
5,571,085	A	11/1996	Accisano, III	

(Continued)

OTHER PUBLICATIONS

Korean Intellectual Property Office, International Application Division, International Search Report for corresponding International Application No. PCT/US2015/048002, dated Feb. 18, 2016, 3 pages.

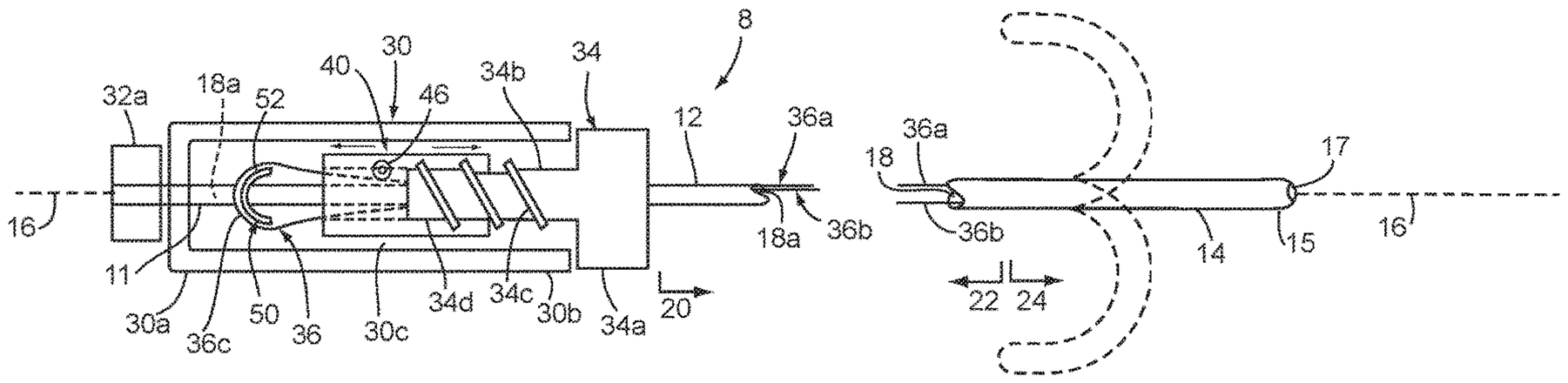
(Continued)

Primary Examiner — Nathan R Price
Assistant Examiner — Courtney Fredrickson
(74) *Attorney, Agent, or Firm* — William A. English; Vista IP Law Group LP

(57) **ABSTRACT**

Deflectable apparatus and methods for performing a procedure within a patient's body using such apparatus are provided. Generally, the apparatus includes an elongate tubular member including a proximal end, a distal end, a longitudinal axis extending between the proximal and distal ends, a deflectable distal portion including first and second lumens spaced apart from one another on generally opposite sides of the longitudinal axis, and a handle coupled to the proximal end of the tubular member. A pull wire includes a loop disposed within the handle and first and second segments extending from the loop and slidably received in the first and second lumens, respectively, and coupled to the distal end. An actuator is provided on the handle for applying tension to either the first or the second segment to cause a distal portion of the tubular member to deflect, e.g., in opposite directions.

22 Claims, 3 Drawing Sheets



(52) **U.S. Cl.**
CPC ... *A61B 2218/002* (2013.01); *A61B 2218/007* (2013.01); *A61M 2025/0166* (2013.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,524,301	B2 *	4/2009	Dubois	A61M 25/0147 604/523
7,691,095	B2	4/2010	Bednarek et al.	
8,308,659	B2	11/2012	Scheibe et al.	
2001/0037084	A1	11/2001	Nardeo	
2012/0089125	A1	4/2012	Scheibe et al.	
2014/0324015	A1 *	10/2014	Romoscanu	A61M 25/0147 604/506

OTHER PUBLICATIONS

Korean Intellectual Property Office, International Application Division, Written Opinion of the International Searching Authority for corresponding International Application No. PCT/US2015/048002, dated Feb. 18, 2016, 7 pages.

* cited by examiner

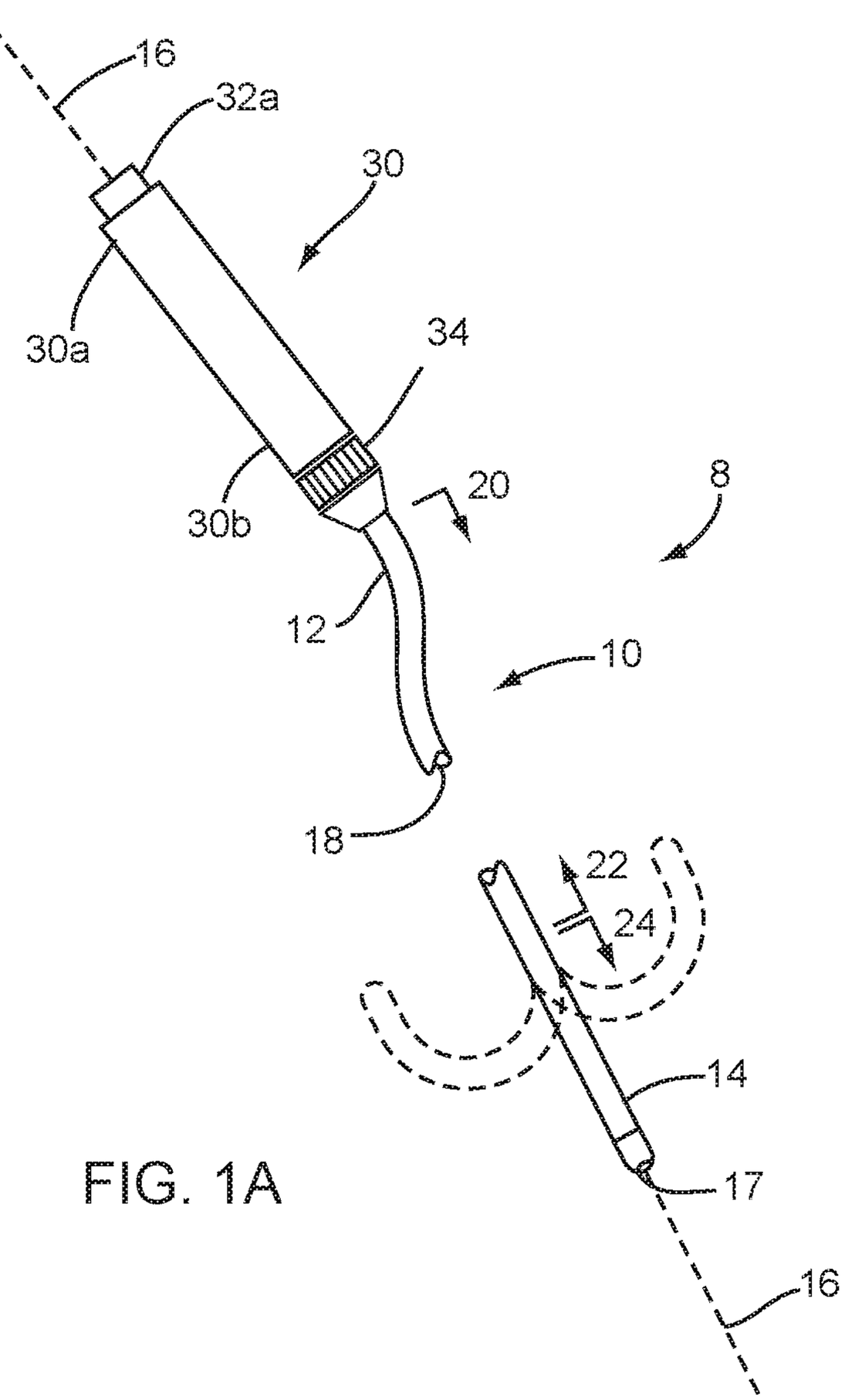


FIG. 1A

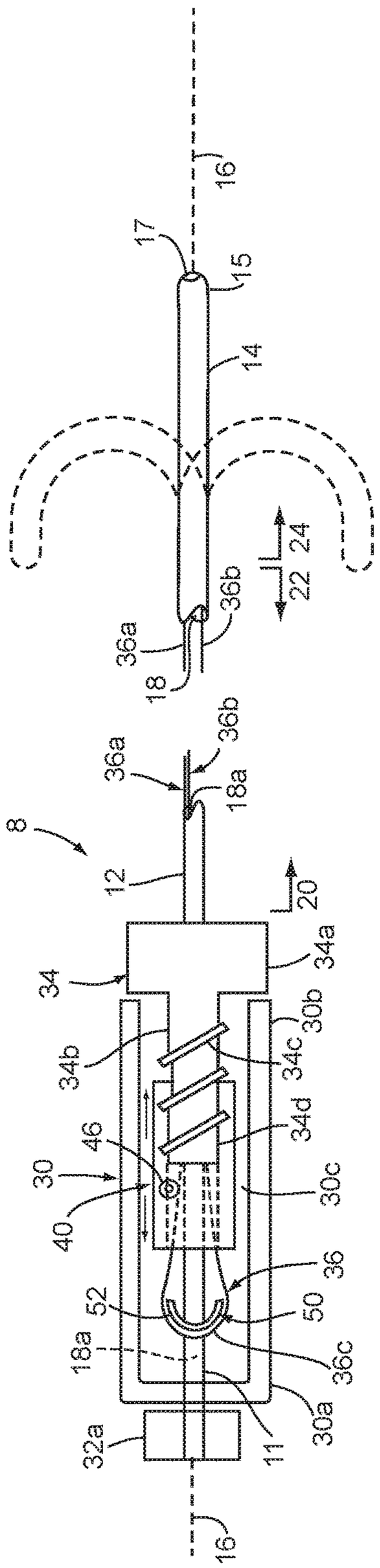


FIG. 1B

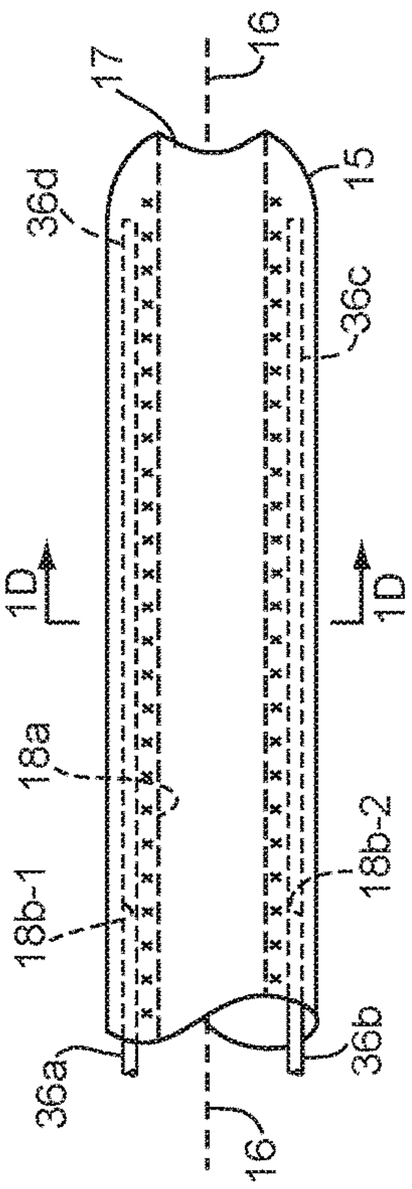


FIG. 1C

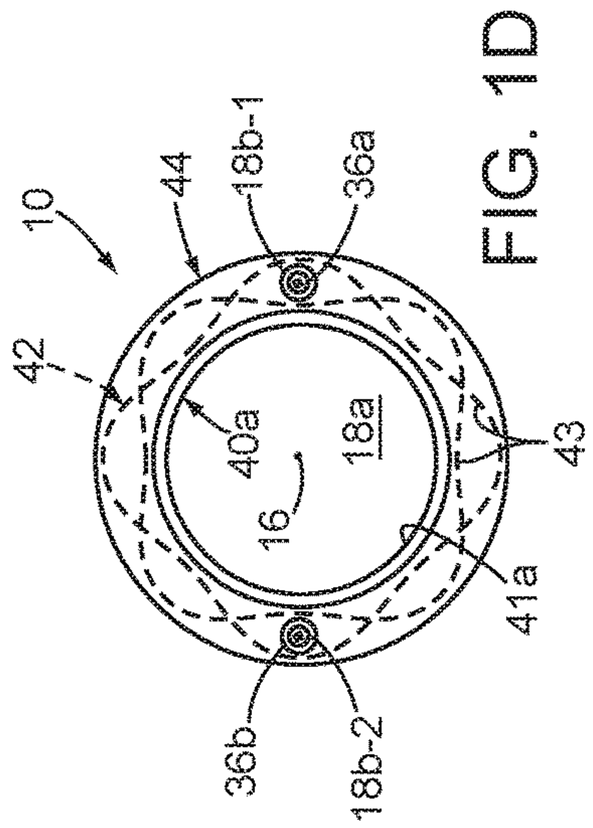


FIG. 1D

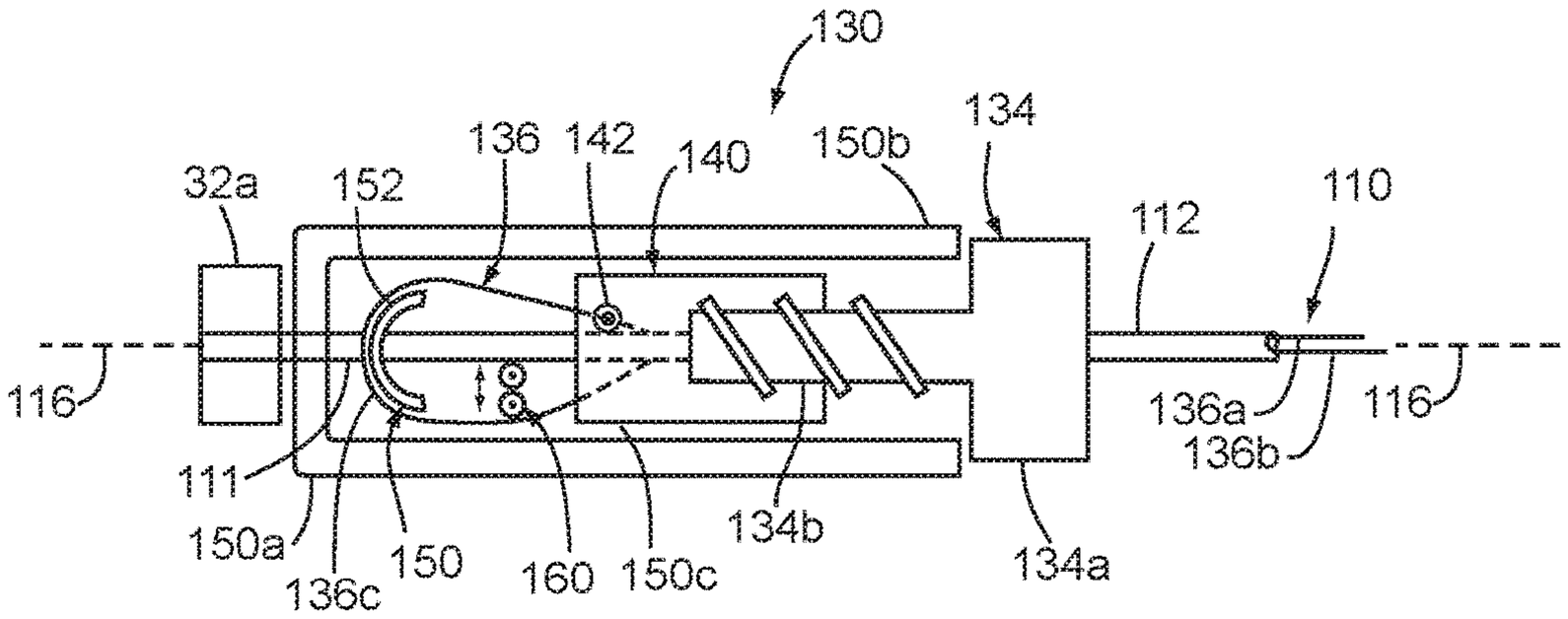

130
134
136
142
140
150b
32a
152
112
110
116
136a
136b
116
111
134b
150a
136c
150
160
150c
134a

FIG. 2

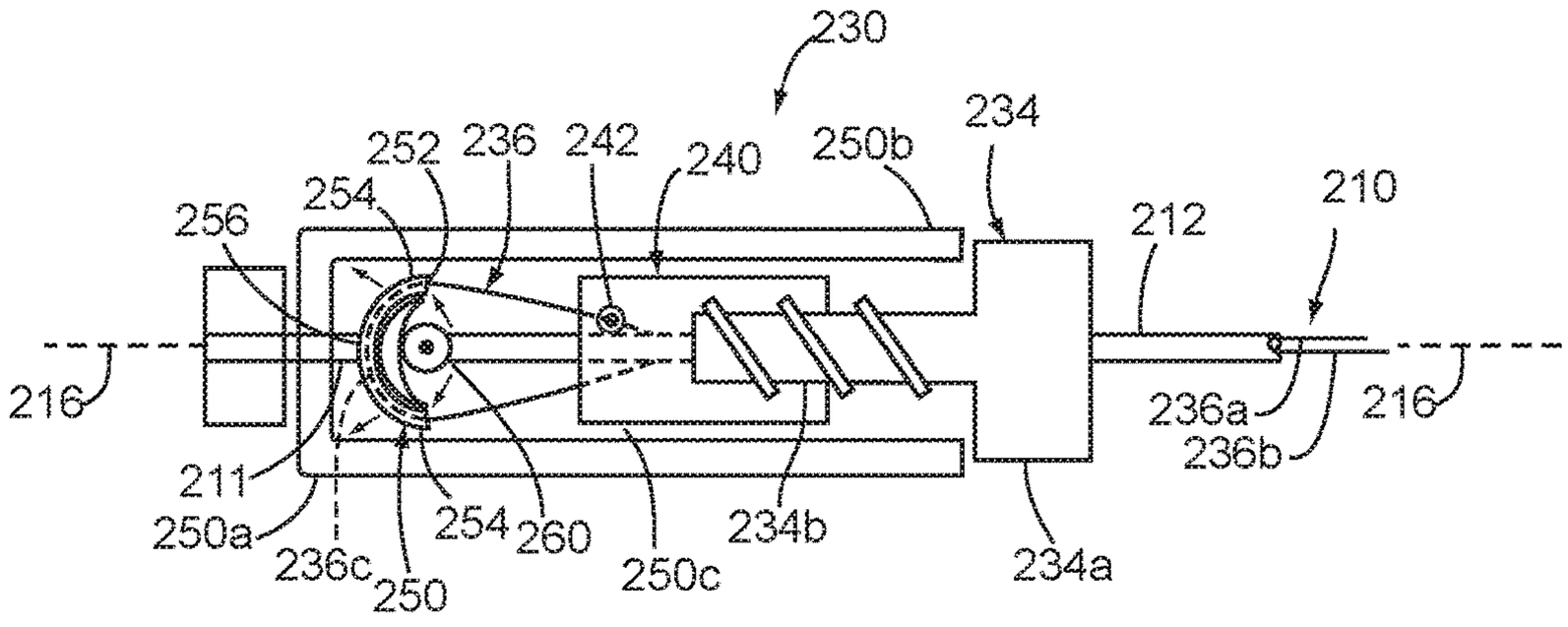

230
234
252
236
242
240
250b
254
210
256
212
216
236a
236b
216
211
250a
236c
254
260
250
250c
234b
234a

FIG. 3

STEERABLE CATHETERS AND METHODS FOR MAKING THEM

RELATED APPLICATION DATA

This application claims benefit of provisional application Ser. No. 62/044,331, filed Sep. 1, 2014, the entire disclosure of which is expressly incorporated by reference herein.

FIELD OF THE INVENTION

The present invention relates generally to catheters, sheaths, or other tubular devices including steerable distal portions, and, more particularly, to handles and actuators for steerable catheters, sheaths, or other tubular devices, and to methods for making such tubular devices and/or handles.

BACKGROUND

Elongate tubular devices, such as diagnostic or treatment catheters or sheaths may be provided for introduction into a patient's body, e.g., the patient's vasculature or other body lumens. For example, a catheter may have a distal portion configured to be introduced into a body lumen and advanced to one or more desired locations within the patient's body by manipulating a proximal end of the catheter.

To facilitate introduction of such a catheter, one or more wires, cables, or other steering elements may be provided within the catheter, e.g., that are coupled to the distal portion and may be pulled or advanced from the proximal end to deflect the distal portion. For example, a steering element may be provided that is intended to deflect the distal portion within a predetermined plane and/or into a desired curved shape.

Pull wires are a common way to impart deflection ability to such a catheter. The pull wire may be slidably disposed within a lumen of the catheter that extends from the proximal end to the distal where a distal end of the pull wire is coupled to the distal end of the catheter. A proximal end of the pull wire may be coupled to an actuator provided on a handle coupled to the proximal end of the catheter. When a proximal tension is applied to the pull wire, e.g., by directing the actuator proximally, it may cause a distal portion of the catheter to curve or otherwise deflect in a first direction. However, the actuator may not be generally directed distally with equal effect to cause the distal portion to curve or deflect in a second opposite direction. Instead, a second pull wire may be provided that be offset from the first pull wire and actuated to deflect the distal portion in the second opposite direction.

Accordingly, there is a need for improved steerable catheters, sheaths, and other tubular devices and for handles and/or actuators for such tubular devices.

SUMMARY

The present invention is directed to catheters, sheaths, or other tubular devices including steerable distal portions. More particularly, the present invention is directed to handles and actuators for steerable catheters, sheaths, or other tubular devices, and to methods for making such tubular devices and/or handles.

In accordance with one embodiment, a deflectable apparatus is provided for performing a procedure within a patient's body that includes an elongate tubular member comprising a proximal end, a distal end, a longitudinal axis extending between the proximal and distal ends, a deflectable distal portion comprising first and second lumens spaced apart from one another on generally opposite sides of the longitudinal axis, and a handle coupled to the proximal end of the tubular member. A pull wire is provided that includes a loop disposed within the handle, a first segment extending distally from the loop through the tubular member and slidably received in the first auxiliary lumen and terminating at a first end coupled to the distal end of the tubular member, and a second segment extending distally from the loop opposite the first segment through the tubular member and slidably received in the second auxiliary lumen and terminating at a second end coupled to the distal end.

The apparatus includes an actuator for applying tension to either the first segment or the second segment to cause a distal portion of the tubular member to deflect, e.g., in opposite directions within a plane. For example, a carriage may be slidably disposed within the handle distal to the loop, the first segment coupled to the carriage at a predetermined distance from the loop. An actuator may be rotatably mounted to the handle and coupled to the carriage for directing the carriage between neutral, proximal, and distal positions within the handle.

In an exemplary embodiment, rotation of the actuator in a first direction with the carriage in the neutral position causes the carriage to move towards the proximal position to apply tension on the first segment and deflect the distal portion in a first direction, and rotation of the actuator in a second direction opposite the first direction with the carriage in the neutral position causes the carriage to move towards the distal position to apply tension on the second segment and deflect the distal portion in a second direction generally opposite the first direction.

In one example, a redirection element may be mounted in the handle proximal to the carriage, and the loop may move relative to the redirection element to apply desired tension to the pull wire. In one embodiment, the redirection element may be a curved wall defining a convex surface directed towards a proximal end of the handle, and wherein the loop may be slidably received around the convex surface such that movement of the carriage between the neutral, proximal, and distal positions causes the loop to slide around the convex surface. In another embodiment, the redirection element may be a U-shaped tube mounted in the handle and the loop may be slidably received in a lumen of the tube.

Optionally, the apparatus may also include a tensioning element for applying a desired tension on the pull wire, e.g., to minimize slack. In one embodiment, the tensioning element may include a pulley movably mounted within the handle at a location such that a portion of the pull wire travels at least partially around the pulley to adjust tension on the pull wire. In another embodiment, where the redirection element is a U-shaped tube, a central portion of the tube is substantially fixed relative to the handle, and wherein ends of the tube are movable to adjust tension on the pull wire. For example, the ends of the tube may be biased away from one another and the loop may be received through the lumen of the tube to cause the ends of the tube to move towards one another to apply a predetermined tension on the pull wire.

Other aspects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings illustrate exemplary embodiments of the invention, in which:

FIG. **1**A is a perspective view of an exemplary embodiment of a catheter, including a steerable distal portion and a handle having an actuator for controlling deflection of the distal portion.

FIG. **1**B is a longitudinal cross-sectional view of the catheter of FIG. **1**A, showing an exemplary embodiment of an actuator within the handle.

FIG. **1**C is a longitudinal cross-sectional view of the distal portion of the catheter of FIG. **1**A, showing auxiliary lumens receiving respective pull wires.

FIG. **1**D is a cross-sectional view of the distal portion of the catheter of FIGS. **1**A-**1**C taken along plane **1**D-**1**D.

FIG. **2** is a cross-sectional detail of an example of a handle including an exemplary embodiment of a tensioning element for applying a desired tension to a pull wire of the catheter.

FIG. **3** is a cross-section detail of another example of a handle including another exemplary embodiment of a redirection element and a tensioning element for applying a desired tension to a pull wire of the catheter.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

Turning to the drawings, FIGS. **1**A-**1**C show an exemplary embodiment of an apparatus **8** for introduction into a body lumen (not shown), e.g., for performing a diagnostic and/or therapeutic procedure within a patient's body. In exemplary embodiments, the apparatus **8** may be a guide catheter, a sheath, a procedure catheter, e.g., an imaging catheter, an ablation and/or mapping catheter, a balloon catheter, or other tubular device sized for introduction into a body lumen, such as a vessel within a patient's vasculature, a passage within a patient's gastrointestinal tract, urogenital tract, reproductive tract, respiratory tract, lymphatic system, and the like (not shown). In exemplary embodiments, the apparatus **8** may have a length between about ten and one hundred ten centimeters (10-110 cm), and an outer diameter between about four and twenty-four French (4-24 Fr).

Generally, the apparatus **8** includes an elongate tubular member **10** including a proximal end **12**, a distal end **14** sized for insertion into a body lumen, a central longitudinal axis **16** extending between the proximal and distal ends **12**, **14**, and one or more lumens **18** extending between the proximal and distal ends **12**, **14**. For example, as shown in FIGS. **1**B and **1**C, the apparatus **8** may include a central or primary lumen **18***a*, e.g., sized for receiving or carrying one or more instruments or other elements (not shown) therethrough. In exemplary embodiments, the central lumen **18***a* may be sized for receiving or carrying a guide wire, procedure catheter, balloon catheter, ablation catheter, cardiac lead, needle, or other instrument (not shown), one or more wires or other conductors, one or more optical fibers, one or more tubes or accessory lumens, one or more mechanical elements, one or more sensors, and/or sized for delivering and/or removing fluids or other flowable agents or materials therethrough.

In one embodiment, the central lumen **18***a* may exit at or communicate with an outlet **17** in the distal end **14**, e.g., to allow a guidewire or other instrument (not shown) to pass therethrough and/or for delivering or aspirating fluid therethrough. In an alternative embodiment, the central lumen may be enclosed, e.g., terminating within or adjacent the distal end **14**, e.g., by an electrode, cap, or other component (not shown) to isolate the central lumen **18***a* and/or elements carried therein from the environment outside the apparatus **8**. In an exemplary embodiment where the apparatus **8** is an ablation and/or mapping catheter, the central lumen **18***a* may carry one or more wires or other conductors, thermocouple wires, tubes, and the like (not shown), e.g., coupled to electrodes or other elements (also not shown) carried on the distal end **14**.

Returning to FIG. **1**C, in addition to the central lumen **18***a*, the tubular member **10** includes a pair of auxiliary lumens **18***b*, e.g., extending adjacent the central lumen **18***a* along at least a distal portion **24** of the tubular member **10**, e.g., substantially parallel to and offset from one another on opposite sides of the central axis **16**. In an exemplary embodiment, each auxiliary lumen **18***b* may be configured to receive a segment of a pull wire or other steering element **36** therein, e.g., to bend or otherwise deflect the distal portion **24** of the tubular member **10**, as described further below. Optionally, the tubular member **10** may include one or more additional lumens (not shown), e.g., one or more additional steering element lumens, inflation lumens (e.g., if the apparatus **8** includes one or more balloons, not shown on the distal end **14**), and/or accessory lumens.

In addition, the apparatus **8** includes a handle **30** coupled to the proximal end **12** of the tubular member **10** that includes one or more actuators, e.g., a rotatable actuator **34** for deflecting a distal portion **24** of the tubular member in a desired manner, as described further elsewhere herein. For example, the actuator **34** may be coupled to the steering element **36** for selectively pulling first and second segments **36***a*, **36***b* received in the auxiliary lumens **18***b* such that proximal tension applied to one of the segments **36***a*, **36***b* causes the distal portion **24** to curve or otherwise deflect in a desired manner, e.g., in a simple curve within a plane or otherwise as described elsewhere herein.

The auxiliary lumens **18***b* may extend separately from the distal end **14** proximally through intermediate and proximal portions **22**, **20** to the handle **30** such that a single steering element **36** may be used that includes a loop **36***c* disposed within the handle **30**, as described further elsewhere herein. As shown in FIG. **1**C, the auxiliary lumens **18***b* may be positioned, over at least a portion of the catheter length, substantially away from the central lumen **18***a* along the distal portion **24**, e.g., to maximize a bending moment applied to the distal portion **24** when proximal tension is applied to one of the segments **36***a*, **36***b*. Along the intermediate and/or proximal portions **22**, **20**, the auxiliary lumens **18***b* may transition to locations closer to the central axis **16**, e.g., to minimize any bending moment applied proximal to the distal portion **24**. Alternatively, a single lumen (not shown) may be provided along the intermediate and/or proximal portions **22**, **20** that separates and/or otherwise communicates with the lumens **18***b*-**1**, **18***b*-**2** in the distal portion **24**.

For example, within the handle **30**, a proximal extension **11** may be provided that extends from the proximal end **12** of the tubular member **10** through the handle **30**. The proximal extension **11** may be coupled to and/or communicate with the hub or port **32***a* on the handle **30**, e.g., including a lumen that communicates with the primary lumen **18***a* of the tubular member **10**. Optionally, the proximal extension **11** may include one or more additional lumens (not shown), e.g., for receiving one or both of the segments **36***a*, **36***b* of the pull wire, as described further below. The hub/port **32***a* may be adjustably coupled to the handle **30** such that the rotational position of the tubular member **10** may be adjusted, e.g., by adjusting and/or fixing the position of the hub/port **32***a* relative to the handle **30**. The proximal extension **11** may be coupled to a proximal end **30***a* of the handle **30** to secure the tubular member **10** relative to the

handle **30** yet may remain uncoupled to a distal end **30***b* of the handle **30**, also as described further below.

Returning to FIG. **1**A, the distal end **14** of the tubular member **10** may include a tapered, rounded, or otherwise shaped distal tip **15**, e.g., to provide a substantially atraumatic tip and/or to facilitate advancement or navigation through various anatomy. In addition or alternatively, the distal end **14** may include one or more therapeutic and/or diagnostic elements, e.g., one or more balloons, stents, sensors, electrodes, ablation elements, thermocouples, steering mechanisms, imaging devices, helical anchors, needles, and the like (not shown), depending upon the particular intended application for the apparatus **8**. Further, in addition or alternatively, the distal end **14** may include one or more features to enhance radiopacity and/or visibility under ultrasound, MRI or other imaging modalities, e.g., by mounting one or more platinum elements on the distal end **14**, doping one or more regions of the distal end **14** with tungsten or barium sulfate, and/or other methods known in the art.

Generally, with particular reference to FIG. **1**D, the tubular member **10** may be constructed to include an inner liner **40**, e.g., at least partially or entirely surrounding or otherwise defining the central lumen **18***a*, a reinforcement layer **42** surrounding the inner liner **40**, and an outer jacket **44** surrounding the reinforcement layer **42**, each of which may extend at least partially between the proximal and distal ends **12**, **14** of the tubular member **10**. The reinforcement layer **42** and/or outer jacket **44** may be attached to the inner liner **40**, e.g., by laminating, adhering, adhesive bonding, ultrasonic welding, reflowing or other heating, and the like, as described elsewhere herein.

In an exemplary embodiment, the central lumen **18***a* is defined by an inner liner **40***a* including an inner surface **41***a*. The inner liner **40***a* may be formed from lubricious material, e.g., PTFE, to provide a lubricious inner surface **41***a*. Alternatively, the inner liner **40** may be formed from one or more layers of thermoplastic or other polymeric material including one or more coatings on the inner surface **41***a* having desired properties, e.g., a hydrophilic and/or lubricious coating, e.g., similar to the liners disclosed in U.S. Pat. Nos. 7,550,053 and 7,553,387, and U.S. Publication No. 2009/0126862, the disclosures of which are expressly incorporated by reference herein.

Optionally, an inner liner may also at least partially surround each of the auxiliary lumens **18***b* (not shown), which may be formed from a lubricious material and/or may include one or more coatings on its inner surface, similar to the inner liner **40***a*. The inner surface of the auxiliary lumens **18***b* may have a substantially uniform cross-section. Alternatively, the inner surface of the auxiliary lumen **18***b* may have a textured or other variable cross-section along, e.g., along its length and/or about its circumference.

Optionally, any or all of the inner liner **40***a*, reinforcement layer **42**, and/or outer jacket **44** may be formed from multiple layers of like or different materials (not shown), e.g., to provide desired material properties in the different portions of the tubular member **10**. In an exemplary embodiment, the outer jacket **44** may be formed from PEBAX, nylon, urethane, and/or other thermoplastic material, e.g., such that the material of the outer jacket **44** may be heated and reflowed and/or otherwise formed around the components defining the lumens **18**, e.g., as described elsewhere herein.

In one embodiment, one or more of the layers of the tubular member **10** may have a substantially homogenous construction between the proximal and distal ends **12**, **14**. Alternatively, the construction may vary along the length of the tubular member **10** to provide desired properties, e.g., between proximal, intermediate, and distal portions **20**, **22**, **24**. For example, a proximal portion **20** of the tubular member **10** adjacent the proximal end **12** may be substantially rigid or semi-rigid, e.g., providing sufficient column strength to allow the distal end **14** of the tubular member **10** to be pushed or otherwise manipulated from the proximal end **12**, while the distal portion **24** may be substantially flexible. As described further below, the distal portion **24** of the tubular member **10** may be steerable, i.e., may be bent, curved, or otherwise deflected substantially within a steering plane.

The reinforcement layer **42** may include one or more reinforcing members **43**, e.g., wound in a braided or other helical configuration around the inner liner **40***a*, and the outer jacket **44** may include one or more tubular layers surrounding the reinforcement layer **42** and/or between the reinforcement layer **42** and the inner liner **40***a*. In an exemplary embodiment, the reinforcement layer **42** may include one or more, or a plurality of, round or flat (e.g., rectangular, elliptical, or flat oval) wires, filaments, strands, or other reinforcement members, e.g., formed from metal, such as stainless steel, plastic, glass, woven or twisted fibers, such as aramid, and the like, or composite materials.

The reinforcement layer **42** may be configured to substantially transfer torsional forces between the proximal and distal ends **12**, **14**, e.g., to allow the tubular member **10** to be twisted from the proximal end **12** to rotate the distal end **14** about the longitudinal axis **16** within a patient's body. In addition, the reinforcement layer **42** may allow the distal end **14** of the tubular member **10** to be advanced or otherwise manipulated within a patient's body from the proximal end **12** without substantial risk of buckling and/or kinking. Optionally, the pitch of the reinforcement layer **42** may be varied along the length of the tubular member **10**, as desired, e.g., in order to optimize mechanical properties of various segments or portions of the tubular member **10**.

In the exemplary embodiment shown in FIG. **1**D, the reinforcement members **43** may be applied around the central lumen **18***a* such that some of the reinforcement members **43***a* including windings that pass between the central lumen **18***a* and the auxiliary lumens **18***b* when wrapped around the central lumen **18***a*, and some of reinforcement members including windings **43***b* that surround both the central lumen **18***a* and the auxiliary lumen **18***b*. Exemplary configurations and methods for making such tubular members are described in U.S. Publication No. 2014/0323964, the entire disclosure of which is expressly incorporated by reference herein.

In an exemplary embodiment, the auxiliary lumens **18***b* may be radially offset from the central axis **16** substantially along the length of the tubular member **10**, e.g., entirely from the distal end **14** to the proximal end **12**, thereby offset from a center of mass of the tubular member **10** along its length. In this embodiment, the non-steerable portions of the tubular member **10** may be constructed to resist bending, e.g., having a substantially greater stiffness than the distal portion **24**, such that any bending moment generated by a pull wire is applied primarily to the distal portion **24**.

Alternatively, along at least the proximal portion **20** and, optionally, along the intermediate portion **22**, a single auxiliary lumen may be provided that receives both segments **36***a*, **36***b* of the pull wire **36** (not shown). In this alternative, the intermediate and/or proximal regions **20**, **20** may be constructed to offset the center of mass from the central axis **16**, e.g., to align the center of mass with the single auxiliary lumen within the intermediate and/or proximal portions **22**,

20 (not shown). For example, the tubular member **10** may have a non-circular or other asymmetrical cross-section that minimizes applying a bending moment to the intermediate and/or proximal portions **22**, **20**, thereby applying any bending moment substantially only to the distal portion **24**.

Optionally, the handle **30** may also include one or more ports, e.g., port **32***a* communicating with the central lumen **18***a*, or other respective lumens (not shown). Optionally, the port **32***a* may include one or more valves, e.g., a hemostatic valve (also not shown), which may provide a substantially fluid-tight seal, while accommodating insertion of one or more instruments or fluids into the central lumen **18***a*. In addition or alternatively, a side port (not shown) may be provided on the handle **30**, e.g., for delivering fluid into and/or aspirating fluid from the primary lumen **18***a*, e.g., around an instrument inserted into the primary lumen **18***a*. Optionally, the handle **20** and/or proximal end **12** may include one or more connectors, such as luer lock connectors, electrical connectors, and the like, for connecting other devices (not shown) to the apparatus **10**, such as syringes, displays, controllers, and the like (also not shown). In addition, the handle **30** may include one or more actuators, such as sliders, buttons, switches, rotational actuators, and the like, e.g., for activating and/or manipulating components (also not shown) on the distal end **14** or otherwise operating the apparatus **10**.

With particular reference to FIGS. **1**A and **1**B, a rotating knob **34** or other actuator, e.g. a sliding actuator, lever actuator, and the like, may be provided on the handle **30** that is coupled to the pull wire **36** by a carriage **40** to deflect the distal portion **24** in a desired manner, e.g., from a neutral position (e.g., a substantially straight configuration shown in FIG. **1**B) to a first deflected configuration (e.g., curved upwardly as shown in phantom in FIG. **1**B) and/or a second deflect configuration (e.g., curved downwardly as shown in phantom in FIG. **1**B), as described further below. In this manner, a single pull wire or steering element **36** may provide bi-directional deflection of the distal portion **24**.

In particular, as shown in FIG. **1**B, the pull wire **36** may include a loop **36***c* disposed within the handle **30**, e.g., cooperating with a redirection element **50** mounted within handle **30**, e.g., adjacent the proximal end **30***a* of the handle **30**. The elongate segments **36***a*, **36***b* may extend enter a lumen of the proximal extension **11** (or separate lumens), e.g., via one or more slots or other openings in a side wall of the proximal extension **11** (not shown) and extend distally from the handle **30**, i.e., through the proximal and intermediate portions **20**, **22** of the tubular member **10** into the respective auxiliary lumens **18***b*-**1**, **18***b*-**2** shown in FIG. **1**C.

The segments **36***a*, **36***b* may be slidably received in the auxiliary lumens **18***b* within the distal portion **24** while distal ends **36***d*, **36***e* of the pull wire **36** may be coupled to the distal end **14** of the tubular member **10**, e.g., adjacent the distal tip **15**, e.g., to a cap, ring, and/or other structure (not shown) on the distal end **14**. With the segments **36***a*, **36***b* otherwise free to slide relative to the auxiliary lumens **18***b*, an axial force on either segment **36***a*, **36***b*, e.g., a proximal force due to pulling on the segment **36***s*, **36***b* from the handle **30** may apply a bending moment to the distal portion **24**, thereby causing the distal portion **24** to curve or otherwise deflect. For example, with additional reference to FIG. **1**B, a proximal force applied to the first segment **36***a* within the handle **30** may cause the distal portion **24** to bend upwardly, while a proximal force applied to the second segment **36***b* may cause the distal portion **24** to bend downwardly, e.g., within the same plane, as indicated by the curved distal portion **24** shown in phantom in FIG. **1**B.

The steering element **36** may be formed from materials capable of substantially transferring any axial forces applied at the proximal end **12** to the distal end **14**, as is known in the art. Optionally, the steering element **36** may include a coating, e.g., PTFE, parylene, silicone, or other lubricious material, an outer sleeve, e.g., formed from HDPE, PTFE, and the like, to reduce friction between the segments **36***a*, **36***b* and the wall of the respective auxiliary lumen **18***b*. Alternatively or in addition, the inner surface of the auxiliary lumens **18***b* may be formed from lubricious material and/or may include one or more coatings, as described elsewhere herein. Alternatively or in addition, the auxiliary lumen **18***b* may include one or more incompressible elements, e.g., a tightly wound coil therearound, e.g., to prevent compression, which may otherwise lead to creating a bending moment along at least part of its length.

With further reference to FIG. **1**B, the handle **30** may include one or more components coupled to the actuator **34** for selectively applying a pulling force on one of the segments **36***a*, **36***b*. For example, the actuator **34** may include a rotatable knob **34***a* mounted to the handle **30**, e.g., adjacent the distal end **30***b* thereof, and a screw **34***b* coupled to the knob **34***a* that extends into an interior **30***c* of the handle **30**, e.g., substantially parallel to the central axis **16** from the distal end **30***b* partially towards the proximal end **30***a* of the handle **30**.

A carriage **40** is slidably disposed within the interior **30***c* of the handle **30**, e.g., between the proximal and distal ends **30***a*, **30***b* that may be movable axially without rotation, e.g., by providing a track or other guide (not shown) within the handle **30** that allows axial movement anywhere between a proximal position and a distal position. The handle interior **30***c* may include one or more adjustable and/or removable stops, e.g., pins, spacers, tabs, and the like (not shown), designed to limit the travel of the carriage **40** within the handle **30** to a predetermined range, e.g., to limit or set the amount of deflection that may be achieved by the distal portion **24**. Alternatively, the range of travel may be selectively adjusted during assembly, e.g. to provide consistent performance across devices despite small variations in positioning, length, compressibility, and or other mechanical characteristics. The carriage **40** may be coupled to the screw **34***b*, e.g., by one or more helical threads or other elements such that rotation of the knob **34***a* causes the screw **34***b* to rotate relative to the handle **30** (without axial movement), thereby translating the carriage **40** axially within the handle **30**. For example, as shown, the screw **34***b* may include one or more threads **34***c* extending helically around a tubular shaft **34***d* and the carriage **40** may include one or more cooperating threads, teeth, and the like that slidably engage one another to transfer rotation of the screw **34***b* into axial movement of the carriage **40**. The configuration of the thread(s), e.g., thread angle, thickness, and/or spacing, may be set such that a desired amount of rotation translates into full proximal or distal movement of the carriage **40**, e.g., from a neutral position.

The carriage **40** and screw **34***b* may include axial passages therethrough along the central axis **16** to accommodate the proximal extension **11** passing through them, e.g., such that proximal extension **11** may extend from the proximal end **30***a* of the handle **30** to the proximal end **12** of the tubular member **10** outside the handle **30** (or the proximal end of the tubular member **10** may enter the handle **30**). Thus, the carriage **40** may move axially over the proximal extension **11**.

In addition, the handle **30** also includes a redirection element **50** that may be mounted within the interior **30***c*

proximal to the carriage **40**, e.g., adjacent the proximal end **30***a* of the handle **30**, that may cooperate with the loop **36***c* of the pull wire **34** to accommodate movement of the segments **36***a*, **36***b* of the pull wire **34**. In the embodiment shown in FIG. **1**B, the redirection element is a curved wall **50** defining a convex surface **52** oriented towards the proximal end **30***a* of the handle **30** such that the loop **36***c* is slidably received around the convex surface **52** and the segments **36***a*, **36***b* extend distally, e.g., into the tubular extension **11** and into the tubular member **10**, as described elsewhere herein. Optionally, the curved wall **50** may be formed from lubricious material, e.g., HDPE, LDPE, nylon, PTFE, FEP, and the like, and/or the convex surface **52** may be coated with a lubricious coating, e.g., a hydrophilic coating or the like, to reduce friction and/or otherwise facilitate the pull wire **36** sliding around the convex surface **52**.

The first segment **36***a* of the pull wire **36** may be coupled to the carriage **40**, e.g., at a predetermined distance from the loop **36***c* and/or redirection element **50**. For example, the carriage **40** may include a set screw or other fastener **46** that may engage a region of the first segment **36***a*, thereby coupling movement of the region to movement of the carriage **40**. In addition or alternatively, the first segment **36***a* may be bonded, welded, soldered, and/or otherwise attached to the carriage **40**. One advantage of a fastener is that the region of the first segment **36***a* engaged by the fastener **46** may be adjusted if desired, e.g., during final assembly and/or configuration of the apparatus **10**, by loosening the fastener **46**, moving the first segment **36***a* axially, and then securing the fastener **46** again. For example, after ensuring that the distal portion **24** is in a neutral, e.g., substantially straightened, configuration with forces balances between the first and second segments **36***a*, **36***b*, the fastener **46** may then be used to secure the first segment **36***a* to the carriage **40**. Alternatively, the carriage **40** may include an attachment mechanism (not shown) that is constructed to attach to the first and/or second segments **36***a*, **36***b*. The attachment mechanism may be adjustably coupled to the carriage **40** such that its position relative to the carriage **40** may be easily adjusted, thereby altering the position of the attachment point of the segments **36***a*, **36***b* to the carriage **40**.

With the first segment **36***a* coupled to the carriage **40**, movement of the carriage **40** causes the pull wire **36** to move and slide around the convex surface **52**. In particular, if the carriage **40** is directed proximally (e.g., by rotating the actuator **34** in a first direction), a proximal pulling force is applied to the first segment **36***a* of the pull wire **36** (distally beyond the secured region), thereby causing the distal portion **24** to deflect, e.g., upwardly as shown in FIG. **1**B and described elsewhere herein. The portion of the pull wire **36** defining the loop **36***c* may slide around the convex surface **52**, thereby lengthening the second segment **36***b* of the pull wire **36** and shortening the first segment **36***a* (relative to the loop **36***c*), which may prevent slack from occurring along the pull wire **36**.

Conversely, if the carriage **40** is directed distally (e.g., by rotating the actuator in a second direction opposite the first direction), a distal pulling force may be applied to the first segment **36***a* of the pull wire **36** (proximal to the secured region), which may translate through the loop **36***c* to apply a proximal force to the second segment **36***b*, thereby causing the distal portion **24** to deflect in the opposite direction, e.g., downwardly as shown in FIG. **1**B. Again the portion of the pull wire **36** defining the loop **36***c* may slide around the convex surface **52**, thereby lengthening the first segment **36***a* of the pull wire **36** and shortening the second segment **36***b* (relative to the loop **36***c*). The second segment **36***b* may slidably pass through the carriage **40**, e.g., in order to guide its path through the handle **30**.

During manufacturing and/or assembly of the apparatus **8**, the tubular member **10** may be fabricated using known materials and/or methods, such as those described in U.S. Publication No. 2014/0323964, incorporated by reference herein. The components of the handle **30**, e.g., including the actuator **34**, carriage **40**, and/or redirection element **50** may also be formed using known materials, e.g., plastic, metal, or composite materials, and methods, e.g., molding, casting, machining, and the like. For example, the outer casing of the handle **30** may be formed from a pair of clamshell halves (not shown) molded or otherwise formed to allow access to the interior **30***c* for positioning the internal components, as desired. Some features, such as the curved wall **50** and/or track or guide (not shown) for the carriage **40** may be integrally molded or otherwise formed into one or both of the halves. After the internal components are assembled, the halves may be substantially permanently attached together, e.g., using one or more of cooperating connectors, bonding with adhesive, fusing, and the like.

For example, the proximal extension **11** may be positioned within the interior and coupled to the proximal end **30***a* of the handle **30**, e.g., again using one or more of cooperating connectors, bonding with adhesive, fusing, and the like, and then the carriage **40** and screw **34***b* may be inserted over the proximal extension **11** such that the carriage **40** is slidable along the track or guide and the knob **34***a* of the actuator **34** is positioned adjacent the distal end **30***b* of the handle **30**.

The pull wire **36** may be placed within the handle **30**, e.g., by directing a central region around the convex surface **52** of the curved wall **50**. Optionally, the carriage **40** may include one or more passages or apertures (not shown) for slidably receiving a portion of the segments **36***a*, **36***b*, e.g., to guide the pull wire **36** from the loop **36***c* into the proximal extension **11** and/or otherwise out the distal end **30***b* of the handle **30**.

The segments **36***a*, **36***b* of the pull wire **36** may be directed into the proximal end **12** of the tubular member **10**, e.g., into a single or separate auxiliary lumens along the proximal portion **20** and/or intermediate portion **22**, and then into the separate auxiliary lumens **18***b*-**1**, **18***b*-**2** shown in FIG. **1**C. The proximal end **12** of the tubular member **10** may be attached to the proximal extension **11**, e.g., adjacent the distal end **30***b* of the handle **30** also using known methods, e.g., one or more of cooperating connectors, bonding with adhesive, fusing, and the like. Alternatively, the proximal extension **11** may be a continuation of the tubular member **10**. The auxiliary lumens **18***b*-**1** and **18***b*-**2** may extend into the proximal extension **11** and exit the sidewall thereof, e.g., midway through the handle **30**. The ends **36***d*, **36***e* of the pull wire **36** may be coupled to the distal end **14** of the tubular member **10**, e.g., before or after attaching the tubular member **10** to the proximal extension **11**, and/or before or after a shaft assembly, e.g., including the tubular member **10** and proximal extension **11**, is placed into the handle **30**. For example, the ends **36***d*, **36***e* may be attached to the distal end **14** itself, e.g., again using one or more of cooperating connectors, bonding with adhesive, fusing, and the like. Alternatively, the ends **36***d*, **36***e* may be coupled to a cap, ring, or other component (not shown) attached to the distal end **14**, as described elsewhere herein.

Before coupling the ends **36***d*, **36***e* of the pull wire(s) **36**, desired excess pull wire material may be cut or otherwise removed, e.g., to provide a desired length extending through

the tubular member **10** to the loop **36***c* within the handle **30**. The first segment **36***a* of the pull wire may be coupled to the carriage **40**, e.g., using one or more fasteners or other methods, as described elsewhere herein, before or after coupling the ends **36***d*, **36***e* to the distal end **14**. The ends **36***a* and **36***b* of the pull wire(s) **36** may be joined to form a loop **36***c* and/or the segments **36***a*, **36***b* may be attached at a common location, e.g., to the carriage **40** as described elsewhere herein.

For example, the relative length and tension applied to the segments **36***a*, **36***b* may be set to minimize slack within the apparatus **8** and/or to balance the inherent tensions in the segments **36***a*, **36***b*, e.g., to bias the distal portion **24** of the tubular member **10** to a desired neutral configuration, e.g., a substantially straightened or other desired shape. Optionally, a desired compressive force may be applied to the tubular member **10**, e.g., between the proximal and distal ends **12**, **14** before finally coupling the pull wire **36** such that segments **36***a*, **36***b* remain under a predetermined axial tension. The tubular member **10** and/or proximal extension **11** may be constructed to provide a predetermined axial tension. For example, a portion of the tubular member **10** and/or proximal extension **11** may be constructed of an elastically compressible material, e.g., urethane, PEBA, and the like, of a predetermined durometer, thickness, and/or length in order to achieve a desired spring effect.

Alternatively or in addition, the tubular member **10** and/or proximal extension **11**, e.g., the catheter shaft may include a range of stiffnesses and/or transitions along its length, e.g., as described elsewhere herein, for the purpose of disposing bending to a distal segment. Additionally, the segment of the shaft passing through the handle **30** may be selectively reinforced, e.g., to resist axial compression in order to further concentrate compression and thereby bending action at the distal portion **24** of the tubular member **10**, e.g., to provide more responsive deflection of the distal portion **24**. Reinforcement of the proximal portion **20** may be achieved by thickening the wall substantially, e.g., compared to the intermediate and/or distal portion **22**, **24** of the tubular member **10**, e.g., sized to enter the body, by altering the reinforcing layer, e.g., optimizing the braid pattern for compression resistance, by including axial reinforcing member in the proximal wall of the shaft, e.g., wires, cables, and the like, and/or by overlaying a compression resistant element, e.g., a hypotube and the like over the proximal shaft.

In another alternative, a pair of pull wires (not shown) may be provided that include distal ends coupled to the distal end **14** of the tubular member **10** (e.g., by welding the distal ends of the pull wires to a ring or other component on the distal end **14**) and extend proximally through the auxiliary lumens **18***b* into the handle **30**. The pull wires may then exit through the side wall of the proximal portion (or extension) of the tubular member **10**, e.g., through side wall openings within the handle **30**, and one or both pull wires may be partially wrapped around the redirection element **50** and proximal ends of the pull wires may be attached or otherwise coupled together, thereby defining the loop **36***c* that extends around the redirection element **50**. Before the pull wires are coupled together, the pull wires may be pulled to stretch or compress the tubular member **10** as desired, e.g., to apply a desired tension to the pull wires, and any excess pull wire may be cut or otherwise removed.

In addition or alternatively, a tensioning element may be provided within the handle **30** to apply a desired tension to the segments **36***a*, **36***b*. For example, as shown in FIG. **2**, another embodiment of a handle **130** is shown (with like features identified with similar reference numbers but increased by 100) that includes a proximal extension **111**, an actuator **134**, a carriage **140**, and 1 redirection element **150**, generally similar to other embodiments herein. The handle **130** or hub **132***a* is coupled to a proximal end **112** of a tubular member **110** or proximal end of the extension **111**, and a single pull wire **136** is provided that includes a loop **136***c* that extends around a convex surface **152** of the redirection member **150** and segments **136***a*, **136***b* that extend into the tubular member **110**, e.g., to the distal end (not shown), also similar to other embodiments herein.

In addition, the handle **130** includes a tensioning element **160** mounted therein that cooperates with one of the segments **136***b* to adjust and/or apply a desired tension to one or both of the segments **136***a*, **136***b*. As shown in FIG. **2**, the tensioning element **160** includes a pulley **160** that is rotatably mounted within the interior **150***c* of the handle **150** such that a portion of the segment **136***b* of the pull wire **136** travels at least partially around the pulley **160** to adjust tension on the pull wire, e.g., before entering the carriage **140** and/or proximal extension **111**.

Optionally, the location of the pulley **160** may be adjusted, e.g., closer to or further away from the central axis **116**, as shown in FIG. **2**, thereby increasing or decreasing tension on the segments **136***a*, **136***b*. For example, a fastener may secure the pulley **160** in a track or slot (not shown), which may be loosened to adjust the location of the pulley **160** and then secured at a desired position along the track or slot to apply a desired tension on the pull wire **136**. In an alternative embodiment, the pulley may be replaced by a guide or other surface that is generally lubricious allowing the one or more segments **136** to slide across it freely.

In an alternative embodiment, the pulley **160** may be movably mounted within the handle **136** and biased to a first position, e.g., away from the central axis **116** by a spring (not shown), yet movable towards a second position, e.g., closer to the central axis **116**, such that the ends of the pull wire **136** (not shown) may subjected to a desired tension before securing them to the distal end of the tubular member **110**, thereby causing the pulley **160** to move away from the first position and the resulting bias applying a predetermined tension on the pull wire.

Turning to FIG. **3**, yet another embodiment of a handle **210** is shown (with like features identified with similar reference numbers but increased by **200**) that includes a proximal extension **211**, an actuator **234**, and a carriage **240**, generally similar to other embodiments herein. The handle **230** may be coupled to a proximal end **212** of a tubular member **210** or the tubular member **212** may enter the handle unattached, and a single pull wire **236** is provided that includes a loop **236***c* and segments **236***a*, **236***b* that extend into the tubular member **210**, e.g., to the distal end (not shown).

Unlike the previous embodiments, the redirection element **250** is a U-shaped tube defining a lumen **252** in which the loop **236***c* of the pull wire **236** may be slidably received. Thus, as the pull wire **236** is actuated, the pull wire **236** may slide through the lumen **252** such that the tube **250** redirects the tension on the second segment **236***b*, similar to other embodiments herein.

Optionally, the handle **230** may include a tensioning element **260** mounted within an interior **250***c* of the handle **250** that cooperates with the tube **250** to adjust and/or apply a desired tension to one or both of the segments **236***a*, **236***b*. As shown, the tensioning element **260** may include a spring **260** mounted adjacent the tube **250** for biasing ends **254** of the tube **250** away from one another. For example, a central portion **256** of the tube **250** may be substantially fixed

relative to the handle **230**, yet the ends **254** may be movable, e.g., to define a higher or lower radius arc. In particular, the ends **254** may be biased to an inner or relatively lower radius arc and the spring **260** may include arms that are biased to push against the ends **254**, e.g., to direct the ends **254** outwardly to a relatively higher radius arc. When the loop **236***c* of the pull wire **236** is received through the lumen **252** of the tube **250**, the ends of the pull wire **236** may be coupled such that a desired tension is applied to the segments **236***a*, **236***b* by the spring **260** and ends **252** of the tube **250**. The tube **250** may be flexible and lubricious, e.g., constructed of HDPE, LDPE, PTFE, FEP, and the like.

The foregoing disclosure of the exemplary embodiments has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many variations and modifications of the embodiments described herein will be apparent to one of ordinary skill in the art in light of the above disclosure.

Further, in describing representative embodiments, the specification may have presented the method and/or process as a particular sequence of steps. However, to the extent that the method or process does not rely on the particular order of steps set forth herein, the method or process should not be limited to the particular sequence of steps described. As one of ordinary skill in the art would appreciate, other sequences of steps may be possible. Therefore, the particular order of the steps set forth in the specification should not be construed as limitations on the claims.

While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the scope of the appended claims.

We claim:

1. A deflectable apparatus for performing a procedure within a patient's body, comprising:

an elongate tubular member comprising a proximal end, a distal end sized for introduction into a patient's body, a central longitudinal axis extending between the proximal and distal ends, and a deflectable distal portion comprising first and second auxiliary lumens spaced apart from one another on generally opposite sides of the longitudinal axis;

a handle coupled to the proximal end of the tubular member;

a single pull wire including a first end and a second end, the pull wire comprising a loop at an intermediate location between the first and second ends disposed within the handle and extending at least partially around a redirection element mounted within the handle, a first segment extending distally from the loop through the tubular member and slidably received in the first auxiliary lumen and terminating at the first end coupled to the distal end of the tubular member, and a second segment extending distally from the loop opposite the first segment through the tubular member and slidably received in the second auxiliary lumen and terminating at the second end coupled to the distal end;

a carriage slidably disposed within the handle distal to the redirection element, the first segment coupled to the carriage at a predetermined distance from the loop; and

an actuator rotatably mounted to the handle and coupled to the carriage for directing the carriage between neutral, proximal, and distal positions within the handle, such that rotation of the actuator in a first direction with the carriage in the neutral position causes the carriage to move towards the proximal position to apply tension on the first segment and deflect the distal portion in a first direction, and rotation of the actuator in a second direction opposite the first direction with the carriage in the neutral position causes the carriage to move towards the distal position to apply tension on the second segment and deflect the distal portion in a second direction generally opposite the first direction.

2. The apparatus of claim **1**, wherein the redirection element comprises a curved wall defining a convex surface oriented towards a proximal end of the handle, and wherein the loop is slidably received around the convex surface such that movement of the carriage between the neutral, proximal, and distal positions causes the loop to slide around the convex surface.

3. The apparatus of claim **2**, wherein the convex surface comprises lubricious material to reduce friction between the loop and the curved wall.

4. The apparatus of claim **2**, further comprising a tensioning element within the handle and coupled to the pull wire for adjusting tension on the pull wire.

5. The apparatus of claim **4**, wherein the tensioning element comprises a pulley movably mounted within the handle at a location such that a portion of the pull wire travels at least partially around the pulley to adjust tension on the pull wire.

6. The apparatus of claim **5**, wherein the pulley is biased to a first position and wherein the pull wire causes the pulley to move away from the first position when the first and second ends are coupled to the distal end of the tubular member, the bias applying a predetermined tension on the pull wire.

7. The apparatus of claim **2**, wherein the curved wall is integrally molded into the handle.

8. The apparatus of claim **1**, wherein the redirection element comprises a U-shaped tube mounted in the handle and wherein the loop is slidably received in a lumen of the tube.

9. The apparatus of claim **8**, wherein a central portion of the tube is substantially fixed relative to the handle, and wherein ends of the tube are movable to adjust tension on the pull wire.

10. The apparatus of claim **9**, wherein the ends of the tube are biased away from one another and wherein the loop is received through the lumen of the tube to cause the ends of the tube to move towards one another to apply a predetermined tension on the pull wire.

11. The apparatus of claim **1**, wherein the proximal end of the tubular member is coupled to a proximal end of the handle and wherein a proximal portion of the tubular member extends from the proximal end of the handle through a distal end of the handle.

12. The apparatus of claim **11**, wherein the actuator comprises a knob rotatably mounted adjacent the distal end of the handle and a screw that at least partially surrounds the proximal portion of the tubular member, the screw and carriage comprising cooperating thread elements such that rotation of the knob causes the screw to rotate relative to the handle and proximal portion, thereby translating the carriage axially within the handle.

13. The apparatus of claim **1**, wherein the first segment is coupled to the carriage by a fastener, and wherein the fastener is adjustable to allow the fastener to be loosened and

secured at a new region of the first segment to adjust the neutral position of the pull wire.

14. The apparatus of claim **1**, wherein the single pull wire is formed by separate pull wires comprising proximal and distal ends, the distal ends coupled to the distal end of the tubular member to define the first and second ends, one or both of the separate pull wires partially wrapped around the redirection element, the proximal ends of the separate pull wires coupled together to define the loop.

15. The apparatus of claim **1**, wherein the single pull wire is configured to slide around the redirection element when the actuator is rotated, thereby lengthening one of the first and second segments and shortening the other of the first and second segments to prevent slack from occurring along the single pull wire.

16. The apparatus of claim **1**, further comprising an attachment mechanism adjustably coupled to the carriage and attached to the first and second segments for adjusting a position of an attachment point of the first segment to the carriage.

17. The apparatus of claim **1**, wherein the carriage comprises one or more passages or apertures for slidably receiving the first and second segments to guide the pull wire from the loop into the tubular member.

18. The apparatus of claim **1**, wherein the handle comprises one or more adjustable stops configured to limit the travel of the carriage within the handle to a predetermined range.

19. A deflectable apparatus for performing a procedure within a patient's body, comprising:

an elongate tubular member comprising a proximal end, a distal end sized for introduction into a patient's body, a central longitudinal axis extending between the proximal and distal ends, and a deflectable distal portion comprising first and second auxiliary lumens spaced apart from one another on generally opposite sides of the longitudinal axis;

a handle coupled to the proximal end of the tubular member;

a pull wire comprising a loop disposed within the handle and extending at least partially around a redirection element mounted within the handle, a first segment extending distally from the loop through the tubular member and slidably received in the first auxiliary lumen and terminating at a first end coupled to the distal end of the tubular member, and a second segment extending distally from the loop opposite the first segment through the tubular member and slidably received in the second auxiliary lumen and terminating at a second end coupled to the distal end;

a carriage slidably disposed within the handle distal to the redirection element, the first segment coupled to the carriage at a predetermined distance from the loop;

an actuator rotatably mounted to the handle and coupled to the carriage for directing the carriage between neutral, proximal, and distal positions within the handle, such that rotation of the actuator in a first direction with the carriage in the neutral position causes the carriage to move towards the proximal position to apply tension on the first segment and deflect the distal portion in a first direction, and rotation of the actuator in a second direction opposite the first direction with the carriage in the neutral position causes the carriage to move towards the distal position to apply tension on the second segment and deflect the distal portion in a second direction generally opposite the first direction; and

a tensioning element within the handle and coupled to the pull wire for adjusting tension on the pull wire, the tensioning element comprising a pulley movably mounted within the handle at a location such that a portion of the pull wire travels at least partially around the pulley to adjust tension on the pull wire, and wherein the pulley is movably securable at a plurality of positions within the handle to apply a predetermined tension on the pull wire when secured at one of the positions.

20. A deflectable apparatus for performing a procedure within a patient's body, comprising:

an elongate tubular member comprising a proximal end, a distal end sized for introduction into a patient's body, a central longitudinal axis extending between the proximal and distal ends, and a deflectable distal portion comprising first and second auxiliary lumens spaced apart from one another on generally opposite sides of the longitudinal axis;

a handle coupled to the proximal end of the tubular member;

a curved wall mounted within the handle and defining a convex surface oriented towards a proximal end of the handle;

a pull wire comprising a loop segment disposed within the handle and extending at least partially around the convex surface, a first segment extending distally from the loop segment through the tubular member and slidably received in the first auxiliary lumen and terminating at a first end coupled to the distal end of the tubular member, and a second segment extending distally from the loop segment opposite the first segment through the tubular member and slidably received in the second auxiliary lumen and terminating at a second end coupled to the distal end;

a carriage slidably disposed within the handle distal to the curved wall, the first segment coupled to the carriage at a predetermined distance from the loop segment;

an actuator mounted to the handle and coupled to the carriage for directing the carriage between neutral, proximal, and distal positions within the handle, such that rotation of the actuator in a first direction with the carriage in the neutral position causes the loop segment to slide along the curved surface and the carriage to move towards the proximal position to apply tension on the first segment and deflect the distal portion in a first direction, and rotation of the actuator in a second direction opposite the first direction with the carriage in the neutral position causes the loop segment to slide along the curved surface and the carriage to move towards the distal position to apply tension on the second segment and deflect the distal portion in a second direction generally opposite the first direction; and

a tensioning element within the handle and coupled to the pull wire for adjusting tension on the pull wire, the tensioning element comprising a pulley movably mounted within the handle at a location such that a portion of the pull wire travels at least partially around the pulley to adjust tension on the pull wire, wherein the pulley is movably securable at a plurality of positions within the handle to apply a predetermined tension on the pull wire when secure at one of the positions.

21. The apparatus of claim **20**, wherein the convex surface comprises lubricious material to reduce friction between the loop segment and the curved wall.

22. The apparatus of claim 20, wherein the pulley is biased to a first position and wherein the pull wire causes the pulley to move away from the first position when the first and second ends are coupled to the distal end of the tubular member, the bias applying a predetermined tension on the pull wire.

* * * * *